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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,841	06/25/2003	Richard M. Fleming	037811-0103	2723

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,841	FLEMING, RICHARD M.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-66 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/5/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17, 19, 34, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "vascularity activity". In Stedman's medical dictionary, the term vascularity means: "The condition of being vascular" and the term vascular means "relating to or containing blood vessels". Accordingly, it is not clear what the applicant means by the phrase "measuring vascularity activity" or "increasing vascularity activity"? Since the applicant cannot increase the blood vessels in the targeted area by using dipyridamole but can increase the blood flow to the vessels in the targeted area. Explanation and/or correction is required.

3. Claim 17, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: injecting a vasodilator, injecting a radioactive material to the targeted tissue, then measuring the vascular or mitochondrial activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-9, 11-16, 54, 58, 59, 61, 62, and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson US 5524622 (Wilson).

Wilson teaches A method of detecting inflammation in a gastrointestinal tract of a human subject, comprising the steps of:

X injecting an intravenous dose of at least 0.56 mg/kg of dipyridamole into the subject;

X injecting an intravenous dose of 3.0 mCi thallium-201 into the subject;

X beginning at least three minutes after injection of the thallium-201, monitoring emissions of gamma radiation with a gamma camera to provide images of the gastrointestinal tract and liver of the subject (claim 10). Wilson also used radiopharmaceuticals to mark the abnormal tissue that comprised technetium-99m labelled sistamibi (claim 3), in a dose of 5-20 mCi (col. 6, lines 23+), this dose is overlapping with the dose range recited in instant claim 9. The dipyridamole is injected intravenously in a dose of at least 0.56 mg/kg (claim 7), note that the reference teach a dose of at least 0.56 mg/kg body weight, which reads on the dose recited in instant claim 6 of 0.852 mg/kg. Further, Wilson used the same method to detect cancerous tissue as gastric adenocarcinoma and lymphoma or esophageal adenocarcinoma (col. 1, lines 55+). In claim 6, Wilson discloses that injecting an intravenous dose of

dipyridamole into a subject in a sufficient amount to dilate an arterial supply of the esophagus and stomach of the subject then injecting an intravenous dose of radioactive material into the subject in a sufficient amount to allow its uptake into an inflamed esophageal or gastric mucosa. Since the uptake of the radioactive material is the factor that will be measured for detecting the abnormal tissue, it is expected that the radioactive agent will be injected during the peak vasodilatory effect of dipyridamole. With regard to instant claim 13, the definition of the word "atypia" in Stedman medical dictionary is: state of being not typical, this meaning encompass the inflammatory tissue and consequently, the claim is encompassed into the rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson 5524622 (Wilson) in view of Crane et al. US 5,961,952 (Crane) and further in view of (ML Chiu, JF Kronauge and D Piwnica-Worms, Journal of Nuclear Medicine, Vol 31, Issue 10 1646-1653, "Effect of mitochondrial and plasma membrane potentials on accumulation of hexakis (2-methoxyisobutylisonitrile) technetium(I) in cultured mouse fibroblasts"), hereinafter (Chiu.)

Wilson is applied as explained above. Though Wilson did not disclose the different doses and concentrations recited in instant claims 4, 5, 10, 20, 21, 26, 37, 38, 53, 56, 57, and 60, it is within the skills of an artisan to adjust the doses and drug concentrations in different dosage forms according to patient's condition and needs.

Wilson is deficient in disclosing the use of his diagnostic method to breast tissue, the vascularity activity and the mitochondrial activity.

Crane teaches a method of diagnosing breast tumors, comprising: administering parenterally to a mammal an effective amount of a composition comprising an imaging agent selected from technetium-99n complexes and a pharmaceutically acceptable carrier; and, radio-imaging the mammal to determine whether a breast tumor is present. Crane discloses that TC-99m-sestamibi appears to have a high sensitivity (>90%) and acceptable specificity (>70%) for imaging breast tumors.

Crane did not explain the relation between mitochondria and uptake of TC-99m-sestamibi .

Chieu discloses the TC-99m-sestamibi localizes within the mitochondria of

tissues and the mechanism appears to be the attraction of the lipophilic cationic complex to the negative potential on the inner mitochondrial membrane. Accordingly, it would have obvious at the time the invention was made to benefit from the explanation of Chieu that TC-99m-sestamibi localizes within the mitochondria of tissues and combine the Wilson's knowledge of using dipyridamole before injecting TC-99m-sestamibi to Crane's disclosure of using TC-99m-sestamibi in the diagnosis of breast cancer. The expected results would be a method of detecting abnormal inflammatory, atypic and/or cancerous tissue in a patient.

3. Claims 13, 29, 46, and 63 are objected to because of the following informalities: the word "atypia" is not an adjective that describes the tissue. Accordingly, the term "atypia tissue" should be corrected to "atypic tissue". Appropriate correction is required.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim 6/14/06

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER